MEDICAL POLICY – 7.01.104

Subtalar Arthroereisis

BCBSA Ref. Policy:	7.01.104	
Effective Date:	July 1, 2023	RELATED MEDICAL POLICIES:
Last Revised:	June 12, 2023	None
Replaces:	N/A	

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Introduction

The talus bone is the bone in the foot that joins with the two leg bones. It is commonly called the ankle bone. The talus sits on top of the heel bone (calcaneus), and the joint between the talus and calcaneus is called the subtalar joint. This joint is quite complex because it's responsible for moving the foot in several different directions. If this joint is too flexible, it could result in conditions known as flat feet and talotarsal dislocation. Having flat feet means that when the foot is on the ground there is no space between the middle of the foot — the arch — and the ground. All of the foot touches the ground. Talotarsal joint dislocation causes the middle of the foot to roll inward during walking. In surgery to restrict the movement of the subtalar joint, a small piece of metal is screwed into the naturally occurring small channel between the ankle bone and the heel bone. The implant keeps the subtalar joint from moving too much. The studies on this surgery are small and don't show how well this procedure works over the long term. Published studies also report problems from the surgery and a high number of implants being removed after they were put in. For these reasons, subtalar arthroereisis is considered investigational (unproven).

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Service	Investigational
Subtalar arthroereisis	**Subtalar arthroereisis is considered investigational.**

Note: This policy only applies to subtalar **arthroereisis** (sinus tarsi implant or stent) surgery, a corrective operation to limit range of motion at the subtalar joint in cases of excessive mobility.

Arthrodesis describes a surgical fusion of a joint so that the bones grow together. Subtalar **arthrodesis** (joint fusion) surgery is not addressed in this policy.

Coding

Code	Description
CPT	
0335T	Insertion of sinus tarsi implant
0510T	Removal of sinus tarsi implant
0511T	Removal and reinsertion of sinus tarsi implant
HCPCS	
S2117	Arthroereisis, subtalar

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Related Information

N/A

Evidence Review

Description

Arthroereisis is a surgical procedure that purposely limits movement across a joint. Subtalar arthroereisis (STA) or extraosseous talotarsal stabilization is designed to correct excessive talar displacement and calcaneal eversion by reducing pronation across the subtalar joint. Extraosseous talotarsal stabilization is also being evaluated as a treatment of talotarsal joint dislocation. It is performed by placing an implant in the sinus tarsi, which is a canal located between the talus and the calcaneus.

Background

Subtalar arthroereisis has been performed for more than 50 years, with a variety of implant designs and compositions. The Maxwell-Brancheau Arthroereisis (MBA) implant is the most frequently reported, although other devices such as the HyProCure, subtalar arthroereisis peg, and Kalix are also described in the medical literature. The MBA implant is described as reversible and easy to insert, with the additional advantage that it does not require bone cement. In children, insertion of the MBA implant may be offered as a stand-alone procedure, although children and adults often require adjunctive surgical procedures on bone and soft tissue to correct additional deformities.

Summary of Evidence

For individuals who have flatfoot who receive STA, the evidence includes mainly single-arm case series and a small nonrandomized controlled trial comparing STA with lateral column calcaneal lengthening. The relevant outcomes are symptoms, functional outcomes, and quality of life. The small nonrandomized comparative trial (N=24 feet) is considered preliminary, and interpretation of the case series evidence is limited by the use of adjunctive procedures in addition to STA, creating difficulties in determining the extent to which each modality contributed to the outcomes. Another limitation of the published data is the lack of long-term outcomes, which is of particular importance because the procedure is often performed in growing children. Also, some studies have reported high rates of complications and implant removal. The evidence is

insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have talotarsal joint dislocation who receive STA, the evidence consists of one prospective single-arm study of talotarsal stabilization using HyProCure. Relevant outcomes are symptoms, functional outcomes, and quality of life. Although improvements in pain and function were observed, the current evidence on the use of STA for treatment of talotarsal joint dislocation is insufficient to draw conclusions about treatment efficacy with certitude. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

A search of **ClinicalTrials.gov** in March 2023 did not identify any ongoing or unpublished trials that would likely influence this review.

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2012 Input

In response to requests, input was received through two physician specialty societies and two academic medical centers while this policy was under review in 2012. Input was mixed, with most reviewers considering this procedure to be investigational.

2009 Input

In response to requests, input was received through one physician specialty society (three reviews) and five academic medical centers while this policy was under review in 2009. Input was mixed regarding the medical necessity of arthroereisis.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a U.S. professional society, an international society with U.S. representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

National Institute for Health and Care Excellence

Guidance from the National Institute for Health and Care Excellence (2009) concluded that current evidence on the safety and efficacy of sinus tarsi implant insertion for mobile flatfoot is inadequate in quality and quantity.[15]

American College of Foot and Ankle Surgeons

Piraino et al (2020) published the following Clinical Consensus Statement on the appropriate clinical management of adult-acquired flatfoot deformity: "Subtalar arthroereisis should not be considered as a single corrective procedure for stage IIB AAFD [adult flatfoot]."[16]

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

A number of implants have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process, a sampling of which are summarized in **Table 1**. In general, these devices are indicated for insertion into the sinus tarsi of the foot, allowing normal subtalar joint motion while blocking excessive pronation.

Product Code: HWC.

Table 1. Representative Subtalar Implant Devices Cleared by U.S. Food and Drug Administration[a]

Device	Manufacturer	Date Cleared	510(k) No.
Subtalar MBA®	Integra LifeSciences	07/96	K960692
OsteoMed Subtalar Implant System	OsteoMed	08/03	K031155
BioPro Subtalar Implant	BioPro	09/04	K041936
HyProCure Subtalar Implant System	Graham Medical Technologies	09/04	K042030
MBA resorb Implant	Kinetikos Medical	09/05	K051611
Metasurg Subtalar Implant	Metasurg	05/07	K070441
Subtalar Implant	Biomet Sports Medicine	07/07	K071498
Arthrex ProStop Plus Arthroereisis Subtalar Implant	Arthrex	01/08	K071456
Trilliant Surgical Subtalar Implant	Trilliant Surgical	02/11	K103183
Metasurg Subtalar Implant	Metasurg	08/11	K111265
NuGait™ Subtalar Implant System	Ascension Orthopedic	08/11	K111799
Disco Subtalar Implant	Trilliant Surgical	12/11	K111834
OsteoSpring FootJack Subtalar Implant System	OsteoSpring Medical	12/11	K112658
IFS Subtalar Implant	Internal Fixation Systems	12/11	K113399
The Life Spine Subtalar Implant System	Life Spine	06/16	K160169

[a] FDA 510(k) database search product code HWC (03/08/18)

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History

Date	Comments
04/11/05	Add to Surgery Section - New Policy
06/09/06	Disclaimer and Scope update - No other changes
08/14/07	Replace policy - Policy updated with literature review; references added. No change in policy statement.
01/17/08	Code Updated - CPT code 28725 was removed and added 28735.
06/10/08	Replace policy - Policy updated with literature search; no change to the policy statement. Reference added.
10/13/09	Replace policy - Policy updated with literature search; no change to the policy statement. Reference added.
11/09/10	Replace policy - Policy updated with literature review through July 2010; references added and reordered. The policy statement remains unchanged.
10/11/11	Replace policy – Policy update with literature review through July 2011; reference 11 added; policy statement unchanged. ICD-10 codes added to policy.
06/04/12	Codes updated; CPT 28725 and 29907 removed from the policy as they do not apply.
11/27/12	Replace policy - Policy guidelines revised with addition of clarification for Arthroereisis (joint implant) surgery vs. Arthrodesis (joint fusion) surgery. Rationale section revised based on literature review through June 2012 and; clinical input. References 2, 3, 10, 14-16 added; others renumbered or removed. Policy statement unchanged.
12/04/13	Replace policy. A literature review through August 13, 2013 did not prompt the addition of any new references. Policy statement unchanged. Codes 0335T (new code), 28735 and 28899 added to the policy.
03/11/14	Coding Update. Code 81.18 was removed per ICD-10 mapping project; this code is not utilized for adjudication of policy.
11/20/14	Annual Review. Policy updated with literature review through July 25, 2014 Reference 11 added; others renumbered/removed. Policy statement unchanged.
11/10/15	Annual Review. Policy updated with literature review through August 6, 2015; reference 2 added. Policy statement unchanged.
06/01/16	Annual Review, approved May 10, 2016. Policy statement unchanged. Literature review, no references added. Removed code 28725; it doesn’t apply to this policy.
10/01/17	Annual Review, approved September 21, 2017. Policy updated with literature review through June 22, 2017; no references added. Removed CPT code 28899. Policy statement unchanged.
07/01/18	Annual Review, approved June 22, 2018. Policy updated with literature review through February 2018; no references added. Policy statement unchanged.
01/01/19	Coding update, added new HCPCS codes 0510T and 0511T (new codes effective 1/1/19).

Date	Comments
07/01/19	Annual Review, approved June 20, 2019. Policy updated with literature review through February 2019; no references added. Policy statement unchanged.
07/01/20	Annual Review, approved June 4, 2020. Policy updated with literature review through January 2020; no references added. Policy statement unchanged.
07/01/21	Annual Review, approved June 1, 2021. Policy updated with literature review through January 11, 2021; reference added. Policy statement unchanged. Policy discussed as a potential candidate for archive, but the need for the policy was affirmed.
07/01/22	Annual Review, approved June 13, 2022. Policy updated with literature review through January 17, 2022; no references added. Policy statement unchanged.
07/01/23	Annual Review, approved June 12, 2023. Policy updated with literature review through January 16, 2023; no references added. Policy statement unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.

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